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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,741	04/03/2001	Arthur W. Zikorus	VNUS.501C1	4515

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EXAMINER	
ROY, BAISAKHI	

ART UNIT	PAPER NUMBER
3737	

NOTIFICATION DATE	DELIVERY MODE
08/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	09/825,741	ZIKORUS ET AL.	
	Examiner	Art Unit	
	BAISAKHI ROY	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,16,21,50-72 and 75-97* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,16,21,50-72 and 75-97* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/20/09 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 70-72, and 75-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desinger (6723094) in view of Navarro et al.

Desinger discloses a system and method to treat tissue with the combination of an optical waveguide or visual feedback to identify tissue of interest and a treatment device to treat the tissue. The therapy of treatment may be directed to tumors (col. 8 line 7), thin-walled regions of the body such as the nasal concha (col. 3 lines 29-47), and may also be a hollow anatomical structure comprising veins such as varicose veins (col. 8 lines 47-49). The treatment is directed to reduced diameter of enlarged vessels where the electrical energy causes the blood and the vessel wall to coagulate causing

the vessel to contract and preventing blood from flowing into the vessel and therefore the vessel is not visible through the skin (col. 8 lines 50-56). Therefore this leads to reduced diameter of the vein and ligation or occlusion of the vein. The system and method is directed to a more controlled and focused treatment of tissue by applying therapeutic energy to target tissues and prevent therapeutic energy from being applied to non-target regions for more localized treatment (col. 2 lines 2-4).

The method involves introducing a treatment device or an electrode arrangement 1 which is a component of a surgical instrument or catheter (fig. 1) into the anatomical structure or tissue to be coagulated comprising an elongate shaft or cylinder 10 which forms the distal end of the instrument and adjoining the front cylinder 10 is a tubular outer conductor 20. The exposed outer surface of the front cylinder 10 forms a first electrode 2. The exposed outside surface of the outer conductor 20 forms a second electrode 4. The two electrodes are connected to voltage sources at the proximal end and therefore includes electrically driven energy application device at the working end of the shaft or cylinder or conductor (col. 11 lines 30-47). The energy application device includes the use of resistive coils, conductive and insulating layers in the electrode arrangement to increase the resistance of the electrode arrangement (col. 2 lines 5-15).

The electrode arrangement may also include an optical waveguide 60 or fiber optic device extending centrally through a hollow duct through the inner conductor 14 and in aligned relationship and passing through the front cylinder 10 which passes visible light to the distal tip 12 of the electrode arrangement when the optical waveguide is fed with visible laser light (fig. 4, col. 11-21). Therefore the optical waveguide is an

integrated part of the treatment device but positioned separately from the therapeutic energy device. The treatment device is introduced at the treatment site over the optical waveguide or fiber optic device (col. 12 lines 25-35). The distal tip of the front cylinder containing the optical waveguide is inserted into the tissue site and the light at the tip makes it possible to locate the position of the tip in the tissue site and then implementing treatment at the site (col. 3 lines 29-47). Therefore the tip provides physical engagement of the energy device with the anatomical structure and the light source provides information on the location of the tissue site where to position the therapeutic energy device. Light is emitted in a radial fashion in the form of stray or scattered light (col. 12 lines 48-60).

Even though Desinger teaches treatment of enlarged vessels such as varicose veins and would obviously require treatment of the saphenofemoral junction, Desinger however does not explicitly teach the step of identifying an anatomical junction where two veins intersect. In the same field of endeavor Navarro et al. disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction. It is well known (as disclosed by Navarro) that the leg has a varicose, greater saphenous vein and varicosity in this vein is due to mal-functioning of the saphenofemoral valve with reflux at the saphenofemoral junction (col. 4 lines 24-29). Treatment is thus directed at the saphenofemoral junction comprising enlarged system of blood vessels. Therefore treatment of enlarged varicose veins would obviously require treatment of the reflux at the saphenofemoral junction and the hollow anatomical structure or the vein has a first and second lumen where the

treatment would be conducted intraluminally. The process involves introducing a catheter into the hollow anatomical structure (col. 4 lines 39-49) and identifying the junction based on feedback from the catheter with the use of light emitted from a fiber optic device and an attribute of the light changes upon reaching the junction (col. 4 lines 50-65). The fiber optical line 40 is positioned relative to the saphenopopliteal junction 52 and laser energy in the 500 nm-1100 nm range is delivered to the vessel walls for a certain amount of time at a certain power range and this is continued with compression of the saphenous vein 50 while the fiber optic line 40 is incrementally withdrawn (col. 5 lines 7-39). This shows that the length of the fiber optic line incrementally changes as the attribute of light changes such as the wavelength, frequency, and power of the laser energy source.

The angiocatheter as taught in Navarro et al. is inserted with the help of the fiber optic line for visual guidance or feedback (col. 4 lines 32-43). The method further involves applying energy to the hollow structure at the treatment site via an energy application device at the working end of the catheter so as to lead to a reduced diameter for the hollow structure or occlude the region of interest (col. 5 lines 7-39).

It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Navarro to modify Desinger such that the treatment method is specifically directed to the saphenofemoral junction and this junction is effectively identified and treated by the therapeutic energy device.

4. Claims 5-7, 16, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desinger in view of Navarro as applied to claims above, and further in view of Makower et al. (6190353).

Desinger and Navarro teach the use of distal tips or rounded tips to engage the junction but do not teach the use of a guidewire with a hook shaped tip and do not teach the step of measuring the length of the optical waveguide or the fiber optic line. In the same field of endeavor Makower et al. disclose a catheter assembly 100 with a tissue-penetrating element 102 with a hook shaped tip (fig. 4). The tissue-penetrating element passes from the catheter to form a passageway through the wall of the artery through a tissue located between the artery and vein then through wall of vein and after the first blood flow passageway has been created, a guidewire is passed through the tissue penetrating element 102 or through catheter 100 and through the passageway. The length of the passageway enables the operator to control the tissue-penetrating element such that the tissue-penetrating element 102 creates a passageway 10 of the desired length between the blood vessel within which the catheter is located and the target region (col. 27 lines 42-54). Therefore the length of the guidewire or the tissue-penetrating element is measured and controlled according to the distance between the blood vessel where the catheter is located and the target. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Makower et al. to modify Desinger and Navarro such that the guidewire with the hook shaped tip along with the treatment catheter may be inserted the appropriate distance within the vessel and effectively engage the tissue site or the junction (col. 21 lines 53-col. 22 line 12).

5. Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desinger in view of Navarro and further in view of Makower et al.

Desinger discloses a system and method to treat tissue with the combination of an optical waveguide or visual feedback to identify tissue of interest and a treatment device to treat the tissue. The therapy of treatment may be directed to tumors (col. 8 line 7), thin-walled regions of the body such as the nasal concha (col. 3 lines 29-47), and may also be a hollow anatomical structure comprising veins such as varicose veins (col. 8 lines 47-49). The treatment is directed to reduced diameter of enlarged vessels where the electrical energy causes the blood and the vessel wall to coagulate causing the vessel to contract and preventing blood from flowing into the vessel and therefore the vessel is not visible through the skin (col. 8 lines 50-56). Therefore this leads to reduced diameter of the vein and ligation or occlusion of the vein. The system and method is directed to a more controlled and focused treatment of tissue by applying therapeutic energy to target tissues and prevent therapeutic energy from being applied to non-target regions for more localized treatment (col. 2 lines 2-4).

Therefore the optical waveguide is an integrated part of the treatment device but positioned separately from the therapeutic energy device. The treatment device is introduced at the treatment site over the optical waveguide or fiber optic device (col. 12 lines 25-35). The distal tip of the front cylinder containing the optical waveguide is inserted into the tissue site and the light at the tip makes it possible to locate the position of the tip in the tissue site and then implementing treatment at the site (col. 3 lines 29-47). Therefore the tip provides physical engagement of the energy device with

the anatomical structure and the light source provides information on the location of the tissue site where to position the therapeutic energy device. The electrode arrangement of the therapeutic energy device is moved to treatment locations and as the treatment location is changed, the energy device would have to be stopped and the system (col. 2 lines 53-63) and would obviously therefore include a mechanical stop for stopping the advancement of the catheter.

Even though Desinger teaches treatment of enlarged vessels such as varicose veins and would obviously require treatment of the saphenofemoral junction, Desinger however does not explicitly teach the step of identifying an anatomical junction where two veins intersect. In the same field of endeavor Navarro et al. disclose a method of positioning a catheter proximate to a junction in a hollow anatomical structure such as the sapheno-femoral junction. It is well known (as disclosed by Navarro) that the leg has a varicose, greater saphenous vein and varicosity in this vein is due to mal-functioning of the saphenofemoral valve with reflux at the saphenofemoral junction (col. 4 lines 24-29). Treatment is thus directed at the saphenofemoral junction comprising enlarged system of blood vessels. Therefore treatment of enlarged varicose veins would obviously require treatment of the reflux at the saphenofemoral junction and the hollow anatomical structure or the vein has a first and second lumen where the treatment would be conducted intraluminally. The angiocatheter as taught in Navarro et al. is inserted with the help of the fiber optic line for visual guidance or feedback (col. 4 lines 32-43). The method further involves applying energy to the hollow structure at the treatment site via an energy application device at the working end of the catheter so as

to lead to a reduced diameter for the hollow structure or occlude the region of interest (col. 5 lines 7-39).

It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Navarro to modify Desinger such that the treatment method is specifically directed to the saphenofemoral junction and this junction is effectively identified and treated by the therapeutic energy device.

Desinger and Navarro teach the use of distal tips or rounded tips to engage the junction but do not teach the use of a guidewire with a hook shaped tip and do not teach the step of measuring the length of the optical waveguide or the fiber optic line. In the same field of endeavor Makower et al. disclose a catheter assembly 100 with a tissue-penetrating element 102 with a hook shaped tip (fig. 4). The tissue-penetrating element passes from the catheter to form a passageway through the wall of the artery through a tissue located between the artery and vein then through wall of vein and after the first blood flow passageway has been created, a guidewire is passed through the tissue penetrating element 102 or through catheter 100 and through the passageway. The length of the passageway enables the operator to control the tissue-penetrating element such that the tissue-penetrating element 102 creates a passageway 10 of the desired length between the blood vessel within which the catheter is located and the target region (col. 27 lines 42-54). Therefore the length of the guidewire or the tissue-penetrating element is measured and controlled according to the distance between the blood vessel where the catheter is located and the target. It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Makower et al. to modify

Desinger and Navarro such that the guidewire with the hook shaped tip along with the treatment catheter may be inserted the appropriate distance within the vessel and effectively engage the tissue site or the junction (col. 21 lines 53-col. 22 line 12).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BAISAKHI ROY whose telephone number is (571)272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR
/Baisakhi Roy/
Examiner, Art Unit 3737